



RESPONSE UNDER 37 CFR 1.116  
EXPEDITED PROCEDURE  
EXAMINING GROUP 1642

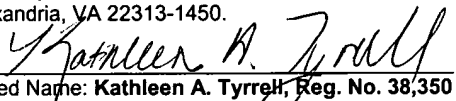
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0184  
Inventors: Roberto A. Macina  
Serial No.: 09/806,311  
Filing Date: July 18, 2001  
Examiner: Helms, Larry Ronald  
Group Art Unit: 1642  
Title: A Novel Method of Diagnosing,  
Monitoring, Staging, Imaging and  
Treating Gastrointestinal Cancers

"Express Mail" Label No. EV583918168US  
Date of Deposit July 12, 2005

I hereby certify that this paper is being deposited  
with the United States Postal Service "Express Mail  
Post Office to Addressee" service under 37 CFR 1.10  
on the date indicated above and is addressed to the  
Mail Stop, Commissioner for Patents, P.O. Box 1450,  
Alexandria, VA 22313-1450.

By

  
Typed Name: Kathleen A. Tyrrell, Reg. No. 38,350

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Petition to Withdraw Holding of Abandonment

Petition is hereby made to withdraw holding of  
abandonment in the instant patent application for failure  
to timely pay the Issue Fee.

Attorney Docket No.: **DEX-0184**  
Inventors: **Roberto A. Macina**  
Serial No.: **09/806,311**  
Filing Date: **July 18, 2001**  
Page 2

Applicants' representative did not receive the original Notice of Allowance mailed December 20, 2004 until July 1, 2005.

Applicants are providing herewith evidence from the electronic filewrapper created by the United States Patent and Trademark Office for the instant application showing return for insufficient address of the original mailed Notice of Allowance to the United States Patent and Trademark Office on April 12, 2005.

Applicants are also providing a copy herewith of the envelope in which the Notice of Allowance was received which is postmarked June 29, 2005.

Applicants are also providing a copy of the Notice of Allowance finally received on July 1, 2005 as indicated by the date stamp.

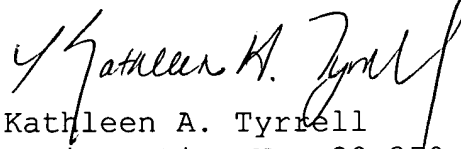
Applicants believe the evidence herein provides adequate support for the United States Patent and Trademark Office to withdraw the holding of abandonment and reset the date for payment of the Issue Fee to September 29, 2005, three months from the actual mailing date of June 29, 2005 of this Notice of Allowance.

Applicants are also submitting the requisite response to the Notice of Allowance, namely the Issue Fee payment, as well as an Amendment under 37 C.F.R. 1.312(a).

Attorney Docket No.: **DEX-0184**  
Inventors: **Roberto A. Macina**  
Serial No.: **09/806,311**  
Filing Date: **July 18, 2001**  
Page 3

Granting of this Petition as well as acceptance of the Issue Fee payment and entry of the amendment under 37 C.F.R. 1.312(a) is earnestly solicited.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: July 12, 2005

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
(856) 810-1515



Organization \_\_\_\_\_ Bldg./Room \_\_\_\_\_

UNITED STATES PATENT AND TRADEMARK OFFICE

P.O. Box 1450

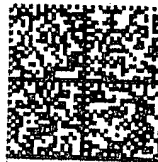
Alexandria, VA. 22313-1450

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Penalty For Private Use, \$300

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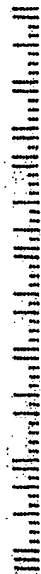
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MAILED FROM ZIP CODE 22202



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Organization: 314g./Room  
U. S. DEPARTMENT OF COMMERCE  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
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TAX

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CH-4058 Zurich

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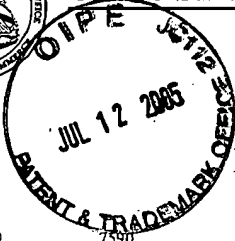
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## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov



## NOTICE OF ALLOWANCE AND FEE(S) DUE

26259

7590

12/20/2004

LICATLA & TYRRELL P.C.  
 66 E. MAIN STREET  
 MARLTON, NJ 08053

EXAMINER

HELMS, LARRY RONALD

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/20/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,311	07/18/2001	Roberto A Macina	DEX-0184	8561

TITLE OF INVENTION: NOVEL METHOD OF DIAGNOSING, MONITORING, STAGING, IMAGING AND TREATING GATROINTESTINAL CANCERS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(\$ ) DUE	DATE DUE
nonprovisional	NO	\$1400	\$0	\$1400	03/21/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

## HOW TO REPLY TO THIS NOTICE:

## I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.
- B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,311	07/18/2001	Roberto A Macina	DEX-0184	8561
26259	7590	12/20/2004		
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				
			EXAMINER HELMS, LARRY RONALD	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 12/20/2004

## Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

# Notice of Allowability

Application No.

09/806,311

Examiner

Larry R. Helms

Applicant(s)

MACINA, ROBERTO A

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to The amendment filed 10/7/04.
2. ☒ The allowed claim(s) is/are 1 and 12-16.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 10/14/04.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER




### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The claims are directed to a method of detecting cancer of the stomach or small intestine by measuring SEQ ID NO:1 or 2 in a sample and patient. The closest prior art is the art of Soppet et al (US Patent 5,861,494, filed 6/95) which teaches detection of colon cancer and metastasis of colon cancer by detection of SEQ ID NO:1 and 2 wherein SEQ ID NO:2 is identical to SEQ ID NO:2 in the instant application. Soppet et al does not teach or fairly suggest a method of detecting stomach or small intestine cancer because Soppet et al uses a colon sample and does not suggest or teach using a sample of stomach or small intestine to determine metastasis or detecting metastasis of colon cancer to the stomach or small intestine.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER

<b>Interview Summary</b>	Application No.	Applicant(s)	
	09/806,311	MACINA, ROBERTO A	
	Examiner	Art Unit	
	Larry R. Helms	1642	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Larry R. Helms. (3) \_\_\_\_\_  
 (2) Ms. Tyrrell. (4) \_\_\_\_\_

Date of Interview: 07 October 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference  
 c) ☒ Personal (copy given to: 1) ☐ applicant 2) ☒ applicant's representative)

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.  
 If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: claim 1.

Identification of prior art discussed: none.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed adding the limitations that the control sample was from the same type of cells, tissues, or body fluid as the patient sample. Ms. Tyrrell will fax a response.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
 Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

<b>Notice of References Cited</b>	Application/Control No. 09/806,311		Applicant(s)/Patent Under Reexamination MACINA, ROBERTO. A	
	Examiner Larry R. Helms		Art Unit 1642	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,861,494	01-1999	Soppet et al.	536/23.1
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

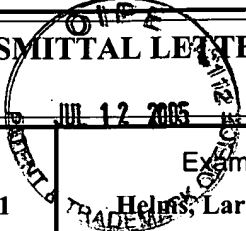
*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<b>AMENDMENT TRANSMITTAL LETTER (Large Entity)</b>					Docket No. <b>DEX-0184</b>	
Applicant(s): <b>Roberto A. Macina</b>						



Application No. <b>09/806,311</b>	Filing Date <b>July 18, 2001</b>	Examiner <b>Helm, Larry Ronald</b>	Customer No. <b>32800</b>	Group Art Unit <b>1642</b>	Confirmation No. <b>8561</b>
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Invention: **A Novel Method of Diagnosing, Monitoring, Staging, Imaging and Treating Gastrointestinal Cancers**

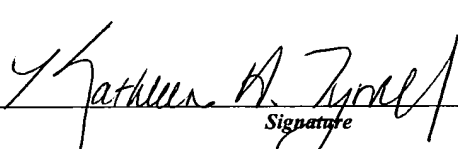
COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.  
The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED						
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE		ADDITIONAL FEE
TOTAL CLAIMS	14 -	20 =	0	x	\$50.00	\$0.00
INDEP. CLAIMS	1 -	3 =	0	x	\$200.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>						\$0.00
<b>TOTAL ADDITIONAL FEE FOR THIS AMENDMENT</b>						<b>\$0.00</b>

☒ No additional fee is required for amendment.  
☐ Please charge Deposit Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_  
☐ A check in the amount of \_\_\_\_\_ to cover the filing fee is enclosed.  
☒ The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account **50-1619**  
     ☒ Any additional filing fees required under 37 C.F.R. 1.16.  
     ☒ Any patent application processing fees under 37 CFR 1.17.  
☒ Payment by credit card. Form PTO-2038.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

  
 \_\_\_\_\_  
 Kathleen A. Tyrrell, Reg. No. 38,350

Dated: **July 12, 2005**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on \_\_\_\_\_  

(Date)

\_\_\_\_\_  
Signature of Person Mailing Correspondence

\_\_\_\_\_  
Typed or Printed Name of Person Mailing Correspondence

CC:



RESPONSE UNDER 37 CFR 1.116  
EXPEDITED PROCEDURE  
EXAMINING GROUP 1642

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0184  
Inventors: Roberto A. Macina  
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Group Art Unit: 1642  
Title: A Novel Method of Diagnosing,  
Monitoring, Staging, Imaging and  
Treating Gastrointestinal Cancers

"Express Mail" Label No. EV583918168US  
Date of Deposit July 12, 2005

I hereby certify that this paper is being deposited  
with the United States Postal Service "Express Mail  
Post Office to Addressee" service under 37 CFR 1.10  
on the date indicated above and is addressed to the  
Mail Stop, Commissioner for Patents, P.O. Box 1450,  
Alexandria, VA 22313-1450.

By Kathleen A. Tyrrell  
Typed Name: Kathleen A. Tyrrell, Reg. No. 38,350

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Amendment under 37 C.F.R. § 1.312(a)

Please enter the following amendments and remarks into  
the record.

Attorney Docket No.: DEX-0184  
Inventors: Roberto A. Macina  
Serial No.: 09/806,311  
Filing Date: July 18, 2001  
Page 2

**Amendments to the specification** begin on page 3.

**Amendments to the claims** are reflected in the listing of claims which begins on page 4 of this paper.

**Remarks** begin on page 7 of this paper.

Attorney Docket No.:       **DEX-0184**  
Inventors:                   **Roberto A. Macina**  
Serial No.:                  **09/806,311**  
Filing Date:                **July 18, 2001**  
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**Amendments to the Specification:**

The title set forth for this patent application in the Notice of Allowance contains a typographical error. Specifically, the term "GATROINTESTINAL" should be --GASTROTINTESTINAL--. Thus, correction of the title to --Novel Method of Diagnosing, Monitoring, Staging, Imaging and Treating Gastrointestinal Cancers-- is respectfully requested.



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This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claim 1 (previously presented): Claim 1: A method for detecting the presence of cancer of the stomach or small intestine in a patient comprising:

(a) measuring levels of CC2 in cells, tissues or bodily fluids from a patient; and

(b) comparing the measured levels of CC2 with levels of CC2 in cells, tissues or bodily fluids from a normal human control sample of the same type of cells, tissues or bodily fluids as the patient, wherein an increase in measured levels of CC2 in said patient versus normal human control sample of the same type of cells, tissues or bodily fluids as the patient is associated with the presence of cancer of the stomach or small intestine, wherein CC2 comprises SEQ ID NO:1 or SEQ ID NO:2.

Claims 2-11 (canceled)

Claim 12: (previously presented) The method of claim 1 wherein the CC2 comprises SEQ ID NO:1.

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Claim 13: (previously presented) The method of claim 1 wherein the CC2 comprises SEQ ID NO:2.

Claim 14: (previously presented) The method of claim 1 wherein CC2 levels are measured in cells from the patient and normal matched human control sample.

Claim 15: (previously presented) The method of claim 1 wherein CC2 levels are measured in tissue from the patient and normal matched human control sample.

Claim 16: (previously presented) The method of claim 1 wherein CC2 levels are measured in bodily fluid from the patient and normal matched human control sample.

Claim 17: (new) The method of claim 1 wherein the cancer detected is cancer of the stomach.

Claim 18: (new) The method of claim 17 wherein CC2 levels are measured in cells from the patient and normal matched human control sample.

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Claim 19: (new) The method of claim 17 wherein CC2 levels are measured in tissues from the patient and normal matched human control sample.

Claim 20: (new) The method of claim 17 wherein CC2 levels are measured in bodily fluids from the patient and normal matched human control sample.

Claim 21: (new) The method of claim 1 wherein the cancer detected is cancer of the small intestine.

Claim 22: (new) The method of claim 21 wherein CC2 levels are measured in cells from the patient and normal matched human control sample.

Claim 23: (new) The method of claim 21 wherein CC2 levels are measured in tissues from the patient and normal matched human control sample.

Claim 24: (new) The method of claim 21 wherein CC2 levels are measured in bodily fluids from the patient and normal matched human control sample.

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**REMARKS**

Claims 1 and 12-16 has been indicated to be allowed in the instant application. New dependent claims 17 through 24 clearly supported by allowed claim 1 and the teachings of the instant specification have been added.

Applicants have also requested correction of a typographical error the title in the Notice of Allowance. Specifically, the term "GATROINTESTINAL" should read --GASTROINTESTINAL--.

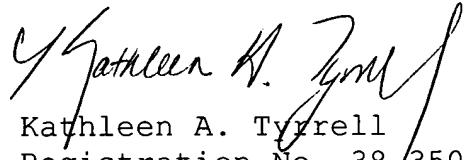
No new matter is added by this amendment. Entry of this amendment is respectfully requested.

Further, in reviewing the file prior to payment of the Issue Fee, Applicants noted that the Examiner did not indicate review of references cited in the Information Disclosure Statement filed by Applicants March 29, 2001. This Information Disclosure Statement is part of the electronic filewrapper created by USPTO for this patent application and therefore is believed to have been considered by the Examiner. It is therefore respectfully requested that the Examiner provide Applicants with an initialed copy of this Information Disclosure Statement.

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In an earnest effort to facilitate this correction of the file, Applicants are providing herewith a courtesy copy of the Information Disclosure Statement wherein initialing by the Examiner is still required.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: **July 12, 2005**

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
(856) 810-1515



09/806311

JCO8 Rec'd PCT/PTO 29 MAR 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0184  
Inventors: Roberto A. Macina  
Serial No.: Not Yet Assigned  
Filing Date: Herewith  
Examiner: Not Yet Assigned  
Group Art Unit: Not Yet Assigned  
Title: A Novel Method of Diagnosing,  
Monitoring, Staging, Imaging and  
Treating Gastrointestinal Cancers

"Express Mail" Label No. EL846058753US  
Date of Deposit: March 29, 2001

I hereby certify that this paper is being deposited  
with the United States Postal Service "Express Mail  
Post Office to Addressee" service under 37 CFR 1.10  
on the date indicated above and is addressed to the  
Assistant Commissioner for Patents, Box PCT,  
Washington, D.C. 20231.

By Deborah Ethel  
Typed Name: Deborah Ethel

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R.  
§§1.97-1.98, information relating to the above-identified  
application is hereby disclosed. Inclusion of information in  
this statement is not to be construed as an admission that this  
information is material as that term is defined in 37 C.F.R.  
§1.56(b).

09/806311

JCOB Rec'd PCT/PTO 29 MAR 2001

- (XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.
- ( ) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
- ( ) Certification in Accordance with §1.97(e) is set forth below; or
- ( ) The fee of \$240.00 as set forth in §1.17(p) is attached.
- ( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(i)(1).
- (XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

09/806311

JCOB rec'd PCT/PTO 29 MAR 2001

( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. @@ filed @@, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

( ) The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,

*Jane Massey Licata*  
Jane Massey Licata  
Registration No. 32,257

Date: March 29, 2001

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Marlton, New Jersey 08053

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JC08 Rec'd PCT/PTO 29 MAR 2001

Form PTO-1449 Modified				Docket No. DEX-0184	Serial No. Not Yet Assigned	
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)				Applicant Roberto A. Macina		
				Filing Date Herewith	Group Not Yet Assigned	
U.S. Department of Commerce Patent and Trademark Office						
U. S. PATENT DOCUMENTS						
Examiner		Document	Date	Name	Class	Subclass
	AA	5,861,494	1-19-99	Soppet et al.	536	23.1
FOREIGN PATENT DOCUMENTS						
Examiner Initial		Document No.	Date	Country	Translation YES	NO
	AB	WO 98/16640	23-04-98	PCT	x	
	AC	WO 96/39541	12-12-96	PCT	x	
EXAMINER				DATE CONSIDERED		

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12 2005

Docket No.  
**DEX-0184**

In Re Application <sup>9</sup> Of: **Roberto A. Macina**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/806,311	July 18, 2001	Helms, Larry Ronald	32800	1642	8561

**Title: A Novel Method of Diagnosing, Monitoring and Staging Small Intestine and Stomach Cancer**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

**Petition to Withdraw Holding of Abandonment with attachments**  
**Amendment under 37 CFR 1.312(a) with attachment**  
**Issue Fee Transmittal**  
**USPTO Credit Card Payment Form authorizing payment in the amount of \$1,436.00**  
**Return postcard**

in the above identified application.

- ☒ No additional fee is required.
- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **50-1619** as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

**Dated: July 11, 2005**

**Kathleen A. Tyrrell, Reg. No. 38,350**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

(Date)

**Signature of Person Mailing Correspondence**

***Typed or Printed Name of Person Mailing Correspondence***

CC: